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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,303	11/27/2001	Robert C. Beck	2446	1374

7590 04/05/2006

Beck & Tysver, P.L.L.C.  
2900 Thomas Avenue S., Suite 100  
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EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

88

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/995,303	BECK, ROBERT C.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Matthew F. DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-9, 18-24 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-9, 18-24 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 7-9, 18-24, 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 7 and 28 are indefinite and unclear because of the term "said wall." The examiner is not sure which structure "said wall" is being comprising. The examiner is not sure if "said wall" is a wall of the vessel, or a wall of the therapy balloon or a wall of the interventional device. Further clarification is needed in the claims as well as an explanation in the remarks section.
4. Claims 7 and 28 also have an antecedent basis problem, because of the recited limitation of said wall in the claims. There is no mention of a wall, as well of the lack of description drawn to the wall structure as mention in the above paragraph.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

Art Unit: 3763

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 7-9, 18-24, 27- 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (USPN 6,524,323).

Nash et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 10, 11, 16, 17; Column 26, line 52 – Column 29, line 40 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath.

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and the injection fluid drops to a second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen.

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection.

7. Claims 7-9, 18-24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (USPN 5100425).

Fischell et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen.

Fischell et al. also discloses an infusion means and a discharge means.  
(Column 5, line 62- Column 6, line 15)

### ***Response to Arguments***

8. Applicant's arguments with respect to the claims have been considered but because of the new issues being raised in the 112 Rejection, the examiner would like to wait and see how the wall structure is related to the other claim limitations before making a final interpretation and final rejection; since the claim language as well as the claim interpretation might change depending on which structure has "said wall" being attached thereto.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

Art Unit: 3763

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto  
Art Unit 3763  
April 3, 2006



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700